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(54) **DEVICE FOR THE IMPLANTATION AND FIXATION OF PROSTHETIC VALVES**

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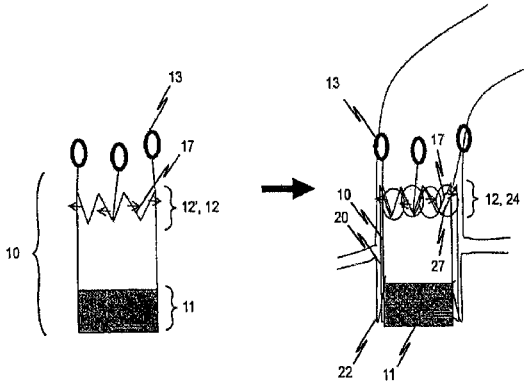
(57) **ABSTRACT**

A device for the transvascular implantation and fixation of prosthetic heart valves having a self-expanding heart valve stent (**10**) with a prosthetic heart valve (**11**) at its proximal end is introducible into a patient's main artery. With the objective of optimizing such a device to the extent that the prosthetic heart valve (**11**) can be implanted into a patient in a minimally-invasive procedure, to ensure optimal positioning accuracy of the prosthesis (**11**) in the patient's ventricle, the device includes a self-expanding positioning stent (**20**) introducible into an aortic valve positioned within a patient. The positioning stent is configured separately from the heart valve stent (**10**) so that the two stents respectively interact in their expanded states such that the heart valve stent (**10**) is held by the positioning stent (**20**) in a position in the patient's aorta relative the heart valve predefinable by the positioning stent (**20**).

9 Claims, 4 Drawing Sheets



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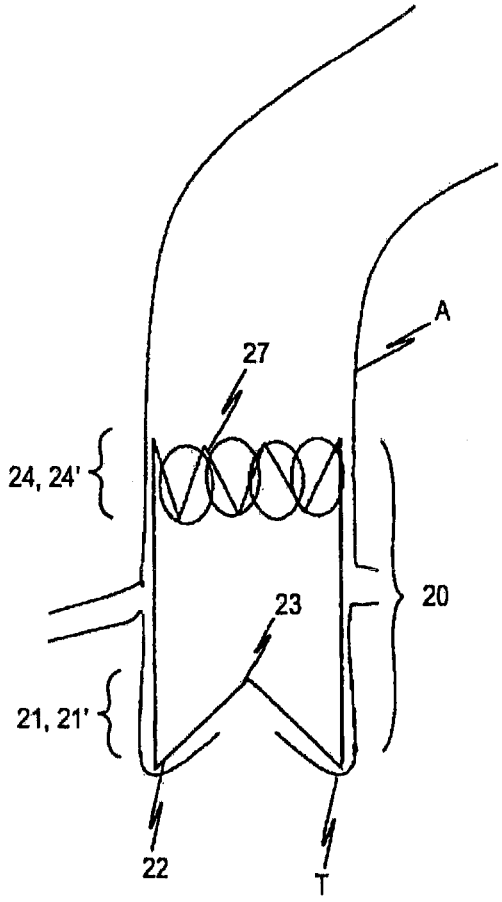
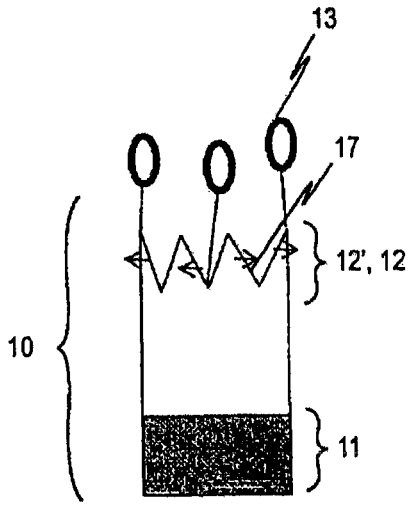


Fig. 1



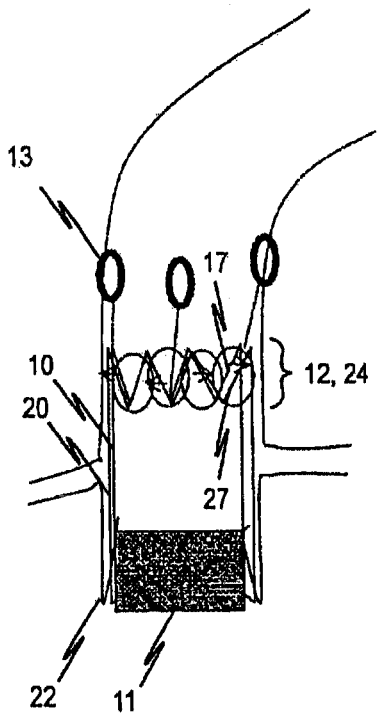


Fig. 2A

Fig. 2B

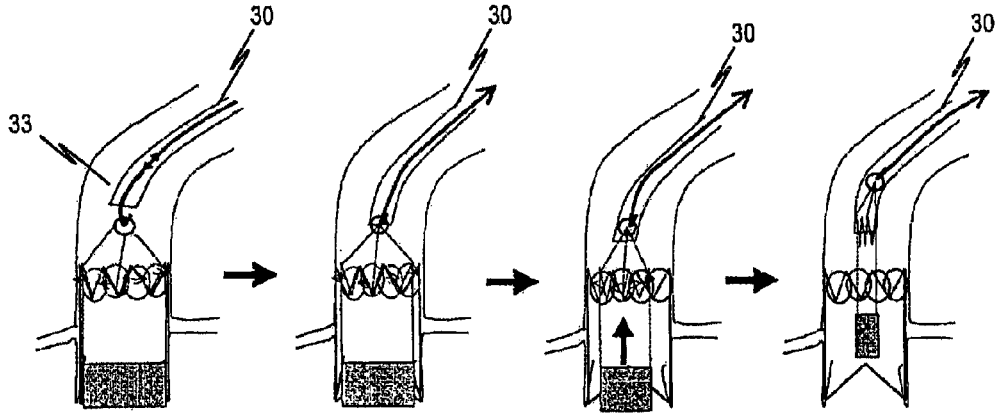


Fig. 3A

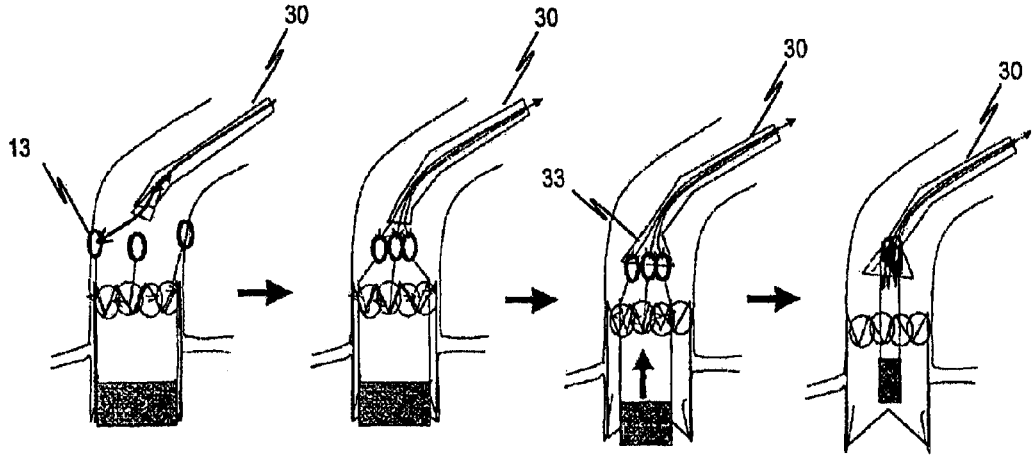


Fig. 3B

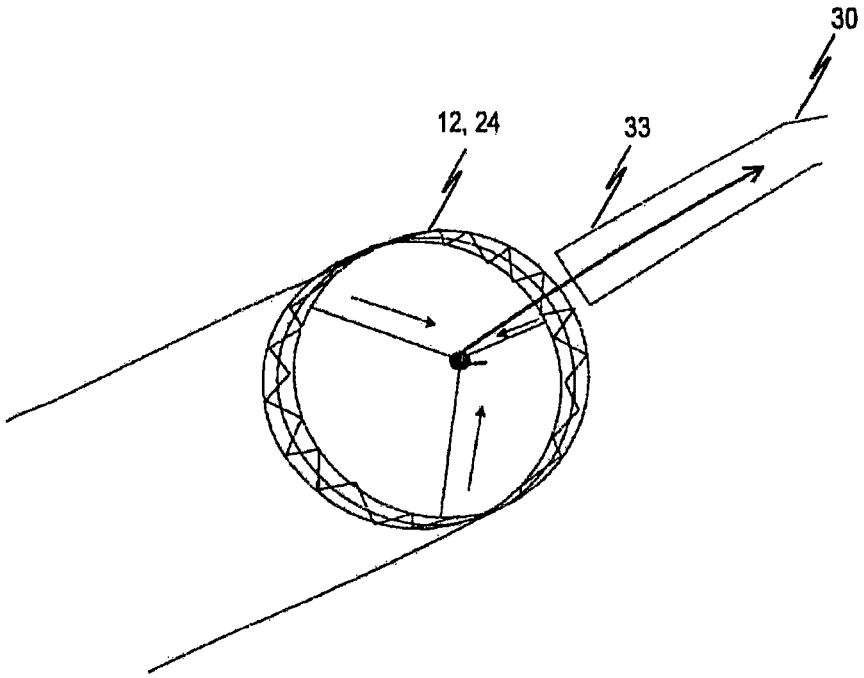


Fig. 4

DEVICE FOR THE IMPLANTATION AND FIXATION OF PROSTHETIC VALVES

This application is a continuation of U.S. application Ser. No. 13/315,913, filed Dec. 9, 2011, which is a continuation of U.S. application Ser. No. 11/589,570, filed Oct. 30, 2006, now U.S. Pat. No. 8,092,521, which claims priority to German Application No. 10 2005 051 849.4, filed Oct. 28, 2005, each of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a device for the transvascular implantation and fixation of prosthetic heart valves having a self-expanding heart valve stent with a prosthetic heart valve at its proximal end.

2. Background Information

A device of this type is, in principle, known to medical technology. At present, biological or mechanical valve models are available to substitute for human heart valves which are usually fixedly sewn into the bed of the heart valve during a surgical procedure through an opening in the chest after removal of the diseased heart valve. In this surgical procedure, the patient's circulation must be maintained by a heart-lung machine, whereby cardiac arrest is induced during the implantation of the prosthetic heart valve. This consequently makes the surgical procedure a risky one coupled with the associated risks for the patients and a lengthy post-operative treatment phase. In particular, such a procedure cannot be performed on patients whose hearts are already too weak.

Minimally-invasive treatment procedures of recent development are characterized in particular by requiring a considerably shortened duration of anesthesia. One approach provides for implanting a self-expanding prosthetic heart valve with an artificial heart valve and a collapsible and expandable stent connected to the heart valve into the human body by means of an appropriate catheter system. The catheter system is used to guide such a self-expanding prosthetic heart valve through a femoral artery or vein to its site of implantation at the heart. After reaching the site of implantation, the stent, which consists for example of a plurality of self-expanding stent segments which can be bent relative one another in the longitudinal direction, can then be successively expanded. Following the expansion, anchoring hooks can for example support the anchoring of the prosthetic heart valve at least in the respective blood vessel close to the heart. The actual prosthetic heart valve itself is thereby in the direct proximal area of the stent.

Known for example from the DE 100 10 074 AI printed publication is a device for fastening and anchoring prosthetic heart valves, which is essentially formed from wire-shaped interconnected elements. The device provides for using various different arched elements in order to attain a secure retention and support for the prosthetic heart valve. To this end, the device described in this printed publication makes use of three identical pairs of arched elements, offset from one another by 120°. These arched elements are interconnected by means of solid articulations, whereby the solid articulations fulfill the function of pivot bearings. Additional arched elements bent opposite to each other are furthermore provided which form, rocker arms as equal in length as possible in order to achieve a secure anchoring of the arched elements even when subject to peristaltic actions on the heart and blood vessels and a solid sealing for an implanted and anchored prosthetic heart valve.

In the known solutions, however, there is a risk of heart valve implant malalignment. This essentially refers to the exact positioning and angular adjustment of the prosthetic heart valve to be implanted. In particular, it is only with immense skill on the part of the person performing the implantation—if at all—that a stent with the prosthetic heart valve at its proximal end winds up being positioned so precisely in the proximity of the patient's diseased heart valve that both sufficient lateral positioning accuracy as well as a suitable angular position to the prosthetic heart valve can be optimally ensured. The known solutions are also only conditionally suitable for explanting improperly or incorrectly positioned prosthetic heart valves. Such a process is usually only possible with great effort; in particular, a further surgical procedure is required.

Among other complications, an implantation malalignment of a less than optimally positioned prosthetic heart valve can lead to, for example, leakage or valvular regurgitation, which puts a substantial burden on the ventricle. Should, for example, a prosthetic heart valve be implanted too high above the actual heart valve plane, this can lead to occlusion of the coronary artery origination (coronaries) and thus to a fatal coronary ischemia with myocardiac infarction. It is therefore imperative for an implanted prosthetic heart valve to meet all the respective requirements for both the accuracy of the lateral positioning as well as the angular positioning.

In conventional implantation techniques in which self-expanding prosthetic heart valves are, for example, guided through a patient's femoral artery to the site of deployment at the heart in a minimally-invasive procedure, the prosthesis is usually introduced using a guide wire and catheters, whereby conventional balloon catheters can also be used. Although such a surgical introduction can be monitored and controlled, for example with fluoroscopy (Cardiac Catheterization Laboratory=CCL) or with ultrasound (Transesophageal Echocardiogram=TEE), oftentimes—due to the limited maneuverability of the prosthetic heart valve which is still in a collapsed state during the introduction procedure and despite being in the collapsed state is still of relatively large size—it is not possible to ensure the required positioning accuracy and especially the angular position to the prosthetic heart valve implant with the corresponding anchoring elements affixed thereto. In particular—as a result of a possible coronary artery occlusion—an angular misalignment to the implanted prosthetic heart valve from the optimum site of deployment can pose a threat to the respective patient.

In designing a prosthetic heart valve, special consideration must, in particular, be given to the substantial forces also acting on the prosthesis during the filling period of the cardiac cycle (diastole), necessitating a secure anchorage in order to prevent the implanted prosthetic heart valve from dislodging.

Hence on the one hand, the prosthetic heart valve must be able to be maneuvered as much as possible in the respective coronary artery during the implantation procedure so as to ensure optimum positioning accuracy and, on the other hand, the implanted prosthesis must be able to be firmly anchored at its site of implantation in order to effectively prevent subsequent prosthesis misalignment.

The present invention addresses the problem that the known devices for transvascular implantation and fixation of prosthetic heart valves are often not suitable for easily implanting a prosthetic heart valve in a patient's ventricle with the necessary positioning accuracy. In particular, the necessary lateral positioning accuracy and the angular position of the prosthetic heart valve can usually only be sufficiently guaranteed when the person performing the procedure has the corresponding experience. On the other hand, explant-

ing a previously implanted prosthetic heart valve in a minimally-invasive procedure or accordingly correcting an incorrectly positioned prosthetic heart valve has to date only been possible with great effort, if at all.

On the basis of this problem as set forth, the present invention proposes a device which enables a prosthetic heart valve to be implanted into a patient in a minimally-invasive procedure in as simple a manner as possible, wherein an increased positioning accuracy to the prosthesis in the patient's ventricle can in particular be ensured. Such a device is to, in particular, reduce the risk of an incorrect deployment to the greatest extent possible.

SUMMARY OF THE INVENTION

According to the invention, this task is solved by a device as described at the outset by the device having, in addition to the self-expanding heart valve stent with a prosthetic heart valve at its proximal end, a self-expanding positioning stent insertable into a position in the patient's aortic valve, which is configured separate from the heart valve stent, wherein the positioning stent and the heart valve stent are configured such that they each work in concert in their expanded states so that the positioning stent helps to hold the heart valve stent in a position relative the patient's heart valve predefined by the positioning stent.

The device according to the invention exhibits an entire array of substantial advantages over the prosthetic heart valves known from the prior art and described above. The two-part configuration of the device in the design of the heart valve stent and the positioning stent configured separately therefrom can, in particular, greatly increase the positioning accuracy of the prosthetic heart valve in the patient's ventricle. The positioning stent hereby primarily assumes the function of determining the position of the prosthetic heart valve in the patient's ventricle as well as the function of anchoring or fixing the prosthesis at optimum placement. In particular, the prosthetic heart valve is not on or in the positioning stent, but instead configured separately from the positioning stent on the heart valve stent. This has the advantage that the dimensions of the positioning stent in its collapsed state are extremely small, which increases the stent's maneuverability.

The heart valve stent primarily serves the inventive device only as a supporting structure for the prosthetic heart valve to be implanted. This function sharing enables both the positioning stent as well as the heart valve stent to be of relatively simple configuration. What can be achieved in particular is that compared to a stent on which both a prosthetic heart valve as well as means for positioning and fixing the prosthetic heart valve are arranged, the positioning stent can be configured to exhibit only relatively small dimensions in its collapsed state. Inserting the positioning stent in the patient's artery is thus—due to the better maneuverability achieved—substantially simpler. A direct consequence of this is increased positioning accuracy for the positioning stem.

The device according to the invention is configured in such a manner that not until the positioning stent is positioned into the patient's artery and after aligning the stent with respect to a predefinable axial rotation and horizontal position relative an (old) heart valve of the patient is the heart valve stent configured separately from the positioning stent inserted into the artery or vein. During the insertion procedure, the heart valve stent, which has the prosthetic heart valve at its proximal end, independently orientates itself to the exactly-positioned positioning stent as fixed at the arterial wall. Specifically, the heart valve stent is independently guided within the expanded positioning stent into the implantation position predefined by the positioning stent at which the prosthetic heart valve is in an optimum position relative the patient's old heart valve. After the heart valve stent, aided by the positioning stent, has positioned into the coronary artery in the predefined position relative the old heart valve, the full expansion of the heart valve stent is induced, for example by an external manipulation, as a consequence of which the heart valve stent according to the invention interacts with the positioning stent in such a way that the heart valve stent, and thus also the prosthetic heart valve disposed at its proximal end, is positionally fixed into the implantation position. Accordingly, the positioning stent serves—in addition to the already mentioned function of defining the position for the prosthetic heart valve in the patient's ventricle and the function of anchoring or fixing the prosthesis at this position—also the function of guiding the heart valve stent into the optimum position for the prosthetic heart valve during the implantation procedure. The advantages attainable with the inventive device are obvious: in particular, an optimum positioning is enabled for the prosthetic heart valve in its final implanted position, whereby the alignment and fixing of the prosthetic heart valve ensues independently based on the co-operative action of the heart valve stent and the positioning stent. On the one hand, a position-contingent, inaccurate implantation of the prosthetic heart valve can hereby be excluded. On the other hand, the device is characterized by the implantation and anchoring of the prosthetic heart valve ensuing in a particularly simple manner.

Because the positioning stent according to the invention is configured to be an insertable, self-expanding component in a patient's blood vessel, it can be inserted beforehand; i.e., prior to the actual implantation of the prosthetic heart valve disposed at the proximal end of the heart valve stent. It would thus be conceivable here for the positioning stent to first be brought into the aorta and optimally positioned and fixed there, whereby the heart valve stent with the prosthetic heart valve is thereafter introduced and inserted optimally by means of the positioning stent already in position and fixed there.

According to the invention, both the heart valve stent as well as the positioning stent are configured to self-expand, which facilitates the respective introduction of these components. Because the positioning stent assuming the task of determining the position for the heart valve stent, the prosthetic heart valve disposed thereon respectively, can be configured to be substantially smaller in comparison to previous self-expanding prosthetic heart valves, the maneuverability of the positioning stent is increased considerably, which ultimately results in being able to select an extremely precise position at which the positioning stent is anchored relative the heart valve and one ideally adapted to the respective requirements. This advantage of exact positioning of the easily-maneuvered and minutely-configured positioning stent extends to the subsequent implantation of the prosthetic heart valve since the heart valve stent, at the proximal end of which the prosthetic heart valve is arranged, is held in the position defined by the (optimally positioned) positioning stent.

Advantageous further developments of the inventive device are specified in the dependent claims.

One particularly advantageous development with respect to insertion of the heart valve stent provides for the heart valve stent to be configured to be reversibly expandable and collapsible. It is thereby conceivable for the heart valve stent to be collapsed, for example via external manipulation, and extracted using an explantation catheter. Specifically, this embodiment enables the heart valve stent in collapsed form to

be connectably received in a cartridge of a positioning catheter, an explantation catheter respectively. In order for the heart valve stent to be optimally inserted into a patient's blood vessel and positioned there in a predefined position relative the heart valve, it is necessary fox the positioning stent to be as small as possible in its collapsed state so that the stent can be optimally navigated with as little impact as possible on the heart valve. This is achieved by the prosthetic heart valve implant not being affixed to the positioning stent but rather to the heart valve stent. The positioning stent is furthermore configured such that all the components of the stent in the collapsed state have a certain measure of pretensioning acting in a radially outward direction which effects the self-expansion following release from the cartridge. The positioning stent can then be implanted with the cartridge in conventional manner using a positioning stent catheter, for example through a femoral artery. Should the positioning stent be inaccurately deployed, for example if the positioning stent is not positioned precisely accurately in the patient's aorta, or when an explantation of the positioning stent is necessary for other reasons, it is provided for the positioning stent to be convertible from its expanded state back into its collapsed state. This is done for example by external manipulation using an implantation catheter. The positioning stent is thus fully reversibly withdrawable in the catheter, which enables the stent to be completely removed.

The inventive device for transvascular implantation and fixation of prosthetic heart valves can advantageously provide for the positioning stent to have an anchorage at its proximal end, in particular an anchoring support, whereby this anchoring support is configured such that the positioning stent self-positions into a pre-defined position relative the patient's heart valve in its expanded state and is held by means of the anchoring support. The positioning stent is thereby configured such that the anchoring support is received in collapsed form in a cartridge connectable with a catheter. The anchoring support is thereby to be compressed such that it is pretensioned in a radially outward direction which effects the self-expansion following release from the cartridge. Configuring the positioning stent so that it self-positions into a given position relative the patient's heart valve in its expanded state and is held there by means of the anchoring support enables the position of the positioning stent and thus the position of the heart valve stem to be precisely definable beforehand so that inaccurate implantations, as can occur with the known solutions, can be excluded.

In order to facilitate the positioning stent's self-expansion, the positioning stent can advantageously furthermore exhibit pretensioning elements in order to radially pretension the positioning stent in its position defined by the anchorage. The pretensioning elements are thereby also configured to be reversible so that their pretensioning function can be countermanded by external manipulation, which enables the positioning stent to be collapsed and thus be retracted into a catheter, enabling the positioning stent to be removed completely.

An advantageous realization of the latter embodiment provides for the anchoring support to have at least one support strut which is configured such that it self-positions into the pockets of the patient's heart valve in the expanded state of the positioning stent and thus fixes the orientation of the positioning stent relative the heart valve in the axial and horizontal direction. Hereby conceivable would be, for example, that the support struts configured at the proximal end of the positioning stent implant independently in the pockets of the respective patient's heart valve during the implantation procedure, whereby the pockets of the heart valve form a counter bearing for counteracting the proximal insertion motion so that the anchoring supports can be precisely positioned laterally with the positioning stent. Since the pockets represent a guide per se for the support struts during insertion, this ensures at the same time that the anchoring support and the positioning stent can adopt a precise angular position. Only after the support struts have been introduced into the pockets of the respective patient's heart valve and the final position for the positioning stent has been reached is the heart valve stent configured separately from the positioning stent deployed with the help of, for example, a heart valve catheter. The heart valve stent exhibiting the prosthetic heart valve at its proximal end is then optimally implanted at the most favorable and ideal site by means of the positioning stent already having been exactly positioned and fixed. To be mentioned as a further advantage is that the support struts of the positioning stent are positioned at the patient's heart valve following implantation of the positioning stent. Because the positioning stent is of relatively simple configuration, since it for example does not comprise the prosthetic heart valve which is disposed separately from the positioning stent on the heart valve stent, the struts of the positioning stent can exhibit a relatively large radius, which entails a lesser risk of injury to the heart valve.

The support strut disposed on an anchoring support or anchorage should be curved convexly and arcuately in the proximal direction because such a rounded form wards off injuries to the heart's blood vessel as well as facilitates the unfolding in the self-expansion process. With such a design, inserting the support struts into the pockets of the old heart valve is thus likewise easier without engendering any corresponding injuries to the tissue or the blood vessels of the region.

Additional stabilizing struts can also be provided on the anchoring supports, which achieves increased fixedness following the self-expansion of the anchored anchoring supports. Such stabilizing struts can be advantageous since in order to benefit from the self-expansion effect required of an anchoring support for securely fixing the anchoring support with the positioning stent, accepting that the anchoring supports collapsed within a cartridge during the introduction phase must be of the smallest volume possible, small cross-sections for the respective struts must be maintained.

All the struts of an anchoring support should thereby be arranged, configured and dimensioned such that the successively ensuing release of the supporting struts and the other struts with the further elements provided on an anchoring support, as the case may be, can be achieved by the appropriate manipulation of cartridge and/or catheter. In so doing, the design of the cartridge or at least a portion of the cartridge should, of course, also be taken into consideration.

Corresponding to physical anatomy, three supporting struts each arranged at the same angular spacing from one another on the anchoring support should be provided. Yet there, is also the possibility of arranging each of the supporting struts disposed on an anchoring support to be at an angular offset from one another. In this case, the supporting struts with their proximal members are then introduced into the pockets of an old heart valve in the implanted state and the old heart valve can then be tightly secured and fixed with the supporting struts.

The stability of an implanted and fixed positioning stent can be optimally increased by means of at least one ring support, which can be an element on an anchoring support. Thus, by means of such a ring support, the possibility exists of connecting different struts provided on an anchoring support,

preferably at their bases. It is thereby not imperative to provide a connection between the ring support and all the struts of an anchoring support.

After the positioning stent is positioned at the heart and held there by the anchorage, the heart valve stent is introduced. It is hereby advantageously provided for the heart valve stent to be configured such that the prosthetic heart valve in its expanded state presses the patient's heart valve against the aorta wall, whereby the at least one anchorage of the positioning stent positions between the aorta wall and the heart valve expanded by the prosthetic heart valve.

In order to have the heart valve stent be held in a position defined by the positioning stent relative the patient's heart valve using the positioning stent, the positioning stent has at least one engaging element at its distal end. The heart valve stent should thereby exhibit a correspondingly complementary-configured retaining element at its distal end, whereby in the expanded state of the positioning stent and in the fully expanded state of the heart valve stent, the at least one retaining element forms a positive connection with the at least one engaging element of the positioning stent. This thus achieves the positioning of the prosthetic heart valve in the coronary artery in the position predefined by the positioning stent and it being held there by the positioning stent. It would hereby be conceivable to provide engaging clips on the heart valve stent. The engaging clips are thereby among the elements of the heart valve stent which are not released to expand until the heart valve stent is accurately inserted into its implantation deployment site at the patient's heart valve by means of the already implanted positioning stent. When the engaging clips of the heart valve stent expand, they engage with the engaging elements of the positioning stent and thus hold the heart valve stent in the position given by the positioning stent. At the same time, portions of the respective patient's old heart valve then each work into an anchoring strut of the positioning stent and the expanded prosthetic heart valve so that the respective portions of the old heart valve can be clamped and held between these elements following the successful expanding of the prosthetic heart valve, similar to how a sheet of paper is held between the brackets of a paper clip.

The heart valve stent is in particular configured such that it does not adopt its fully expanded state, in which both the prosthetic heart valve as well as also the retaining element is released, until the heart valve stent is in the position as defined by the positioning stent.

As is the case with the positioning stent, the heart valve stent is also advantageously configured to be reversible in its folding action, whereby the positive connection with the positioning stent is disengaged in the collapsed state. This thus allows the prosthetic heart valve disposed on the heart valve stent to again be explanted, for example in the case of an improper implantation, without also having to extract the positioning stent in order to do so.

In order to facilitate explantation of the heart valve stent, explantation elements can be provided at the distal end of the heart valve stent which work in concert with the heart valve stent such that when externally manipulated, for example, the explantation elements disengage the positive connection between the heart valve stein and the positioning stent, and the heart valve stew collapses. One advantageous realization of the explantation elements provides for their being engageable, for example by means of an explantation catheter, whereby retracting the explantation elements in the explantation catheter disengages the positive connection between the heart valve stent and the positioning stent, and the heart valve stent folds back up.

The heart valve stent is advantageously accommodated in the collapsed state in a cartridge connectable to a heart valve stein catheter and/or explantation catheter, whereby a predefinable motion of the cartridge will release the heart valve stent. Specifically, it is thereby advantageously provided that a predefinable first motion of the cartridge will only release the prosthetic heart valve to expand, whereby the retaining element of the heart valve stent is released by at least one second subsequent motion of the cartridge, the catheter respectively.

It can be advantageous, in particular for the subsequent cartridge and catheter movement, which leads to the sequential release of the individual elements of the heart valve stent, to use a multi-part cartridge, whereby at least two individual parts can each be moved relative one another. Hence, the movements of a cartridge or individual parts of a cartridge to be realized, for example so as to lead to self-expansion, can be a proximal and/or distal displacement, which can ensue in several successive stages, each covering different paths in order to successively release the corresponding parts for their respective expansion during implantation.

Thus, a first movement, for example, can be a distal retraction of the cartridge or a portion of a cartridge. Should it hereby be necessary so as to avoid inaccurate implantation, a proximal movement of the cartridge or a portion of a cartridge can then be effected to re-collapse the already-expanded retaining elements acting radially outwardly with a pretensioning force, the prosthetic heart valve of the heart valve stent respectively, and to bring same into the interior of the cartridge so as to enable the device to be removed from the patient. Bowden cables or flexible push tubes guided through the interior of the catheter to the cartridge or to a portion of the cartridge can be used as the actuating elements for a manipulation and the associated displacing movement of the cartridge or individual parts of the cartridge. Such actuating elements can, however, also engage with fastening elements, for example eyelets, provided on the anchoring support.

The solution according to the invention thus also provides the possibility of aborting prosthetic heart valve implantations which will be unsuccessful and removing the device again by withdrawing the catheter, whereby in so doing, the heart valve stent which has already expanded re-collapses again and can be guided back into a cartridge or a portion of a cartridge.

An advantageous further development of the device according to the invention provides for the positioning stent to furthermore comprise anchoring elements, in particular hooks, in order to anchor the positioning stent in its predefinable position at the heart. Additionally or alternatively to the positioning stent, it would be conceivable for the heart valve stent to also comprise anchoring elements such as hooks, for example, in order to anchor the heart valve stent in the position in the aorta as predefined by the positioning stent. Both solutions ultimately serve the secure fixing of the implanted prosthetic heart valve at its site of implantation as predefined by the positioning stent.

In order to facilitate spatial orientation when inserting the positioning stent, markers can be disposed on the positioning stent, in particular x-ray markers. Of course, other solutions are also conceivable. For example, insertion of the positioning stent can also be monitored and controlled using fluoroscopy (Cardiac Catheterization Laboratory=CCL) or ultrasound (Transesophageal Echocardiogram=TEE).

The positioning stent and/or the heart valve stent can furthermore exhibit guiding means which are configured in such a manner that the heart valve stent is guided independently in the expanded positioning stent into the position predefined by

the positioning stent. It would hereby be conceivable for the guiding means to be configured as elements tapering to the distal end of the positioning stent, the heart valve stent respectively, so as to realize a self-adjusting of the heart valve stent in the positioning stent and thus into the position predefined by the positioning stent.

The device according to the invention can also be used together with a balloon catheter. With a balloon catheter, the old heart valve can be pushed away prior to the self-expansion of the anchoring support.

The following will make reference to the figures in describing preferred embodiments of the device according to the invention for the implantation and fixation of prosthetic heart valves in greater detail.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1**: a preferred embodiment of a positioning stent of the device according to the invention in the inserted and expanded state;

FIG. **2**A: a preferred embodiment of a heart valve stent of the device according to the invention in the expanded state;

FIG. **2**B: the heart valve stent of FIG. **2**A in the implanted state;

FIGS. **3**A,B: one schematic representation each to illustrate the explantation process with a preferred embodiment of the heart valve stent, and

FIG. **4**: a detailed representation of the explantation elements provided on the heart valve stent, the positioning stent respectively, as well as their mode of operation.

DETAILED DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT

FIG. **1** shows a preferred embodiment of a positioning stent **20** for the device according to the invention in the inserted state. The positioning stent **20** is in its expanded state in the embodiment shown. As depicted, the positioning stent **20** has an anchoring segment **21'** with anchoring supports **21** at its proximal end. The anchoring supports **21** are hereby configured such that they optimize themselves into the pockets T of the old heart valve relative to axial rotation as well as horizontal position. To this end, the positioning stent **20** is supported by means of anchoring supports **21** in pockets T of the old heart valve. The anchoring supports **21** themselves are connected to docking segment **23** by means of shoulders **22**. The docking segment **24'** of positioning stent **20**, provided at its distal end, exhibits a plurality of engaging elements **24** which fix a heart valve stent to be implanted (not explicitly shown in FIG. **1**).

The positioning stent **20** is configured as a self-expanding component. Due to the simple configuration of positioning stent **20**, which essentially consists only of anchoring segment **21'**, docking segment **24'** and shoulders **22**, the positioning stent **20** exhibits extremely small dimensions when in its collapsed state. Thus, when inserting positioning stent **20**, for example using a positioning stent catheter, the positioning stent **20** has very good maneuverability within aorta A. After positioning stent **20** has been inserted into aorta A, it is expanded, enabled, for example, by means of an external manipulation of the positioning stent catheter. The anchoring supports **21** of the expanded positioning stent **20** self-position into the pockets T of the patient's heart valve, whereby the alignment of the positioning stent **20** in the axial and horizontal direction is fixed relative the heart valve. So that the positioning stent **20** will expand independently, suitable pretensioning elements can be (optionally) provided. In the embodiment as shown, pretensioning elements are realized in the form of anchoring supports **21**.

After positioning stent **20** is inserted into aorta A and positioned and fixed there as described above, a heart valve stent **10** (FIG. **2**A) disposed with a prosthetic heart valve **11** at its proximal end is inserted into positioning stent **20**. It expands subsequent to release and, in doing so, presses the old valve against the aorta wall, the positioning stent **20** respectively.

FIG. **2**A shows a heart valve stent **10** in the expanded state. As depicted, the heart valve stent **10** has the prosthetic heart valve **11** at its proximal end and an anchoring segment **12'** comprising at least one retaining element **12** at its distal end.

FIG. **2**B provides a representation of how the heart valve stent **10** is held in the already positioned and fixed positioning stent **20**. The heart valve stent **10** is guided by guide elements **17**, **27** in positioning stent **20** relative to rotation and axial position such that the new heart valve is optimally positioned. Thereafter, further releasing of the heart valve stent **10** introduces its anchoring segment **12'** into docking segment **24'** (FIG. **1**) of the positioning stent **20**. The anchoring segment **12'** comprises retaining elements **12** which form a positive connection with the engaging elements **24** of the positioning stent **10** in order to position the prosthetic heart valve **11** in the position in the coronary artery as predefined by the positioning stent **20** and to hold same there by means of positioning, stent **20**.

Unlike, conventional heart valve stents, the heart valve stent **10** of the present device does not have retaining clips to engage behind the old heart valve but rather engaging clips in the form of retaining elements **12** in the anchoring segment **12'** of heart valve stent **10**. These engaging clips interact with the engaging elements **24** disposed in the docking segment **24'** of positioning stent **20**. The advantage of this is that the heart valve stent **10** is commutably anchored in positioning stent **20**. By means of its self-expanding induced by guide means **17**, **27**, heart valve stent **10** independently slides inside positioning stent **20** and cannot slide any further. The guide means **17**, **27** are configured as elements tapering to the distal end of positioning stent **20** and/or heart valve stent **10**. Due to the special design of engaging elements **23** of positioning stent **20** and the retaining elements **12** of heart valve stent **10** as clips formed in zigzag fashion (Z-clips), a finer angular positioning of the heart valve stem **10** can in particular ensue. Both the positioning stent **20** as well as the heart valve stent **10** can be configured of individual segments, whereby the individual segments can be rotated relative one another. This increases flexibility when inserting the two stents into the aorta. It is in particular possible to realize a finer angular positioning to heart valve stent **10**. It is thus conceivable, for example, for the physician to alternatively insert a rotated prosthetic heart valve **11**. The segmented configuration is also of advantage with respect to the collapsing of the heart valve stent and the positioning stent since the segmented stents in collapsed state can be housed compressed within a catheter.

FIGS. **3**A, **3**B and **4** are schematic representations of how the heart valve stent **10** in the already positioned and implanted positioning stent **20** can be explanted. In the event of a valve dysfunction, the mechanically stable connection between the positioning stent **20** and the heart valve stent **10** as described above can be disengaged again by external manipulation. This can be realized, for example, by using a catheter **30** with a cartridge **33** affixed thereto to engage explantation elements **13**. After retracting the explantation elements **13** into the variable funnel-shaped explantation catheter **30**, the heart valve stent **10** is pulled into same and

can thus be replaced with a new one. The positioning stent **20** remains as a marking and anchoring base for a new heart valve stent **10**. Positioning stent **20** can, of course, also be explanted in a similar procedure.

The docking segment **24'** of the positioning stent can comprise eyelets or nubs to which the explantation catheter **30** is to be affixed in order to effect such an explantation. Attaching to eyelets is possible via preferably three to six eyelets and three to six loops which are subsequently pulled out of the eyelets. The positioning stent **20** as well as the heart valve stent **10** is in particular completely reversibly withdrawable in the catheter, which enables the complete removal of the positioning stent and/or the heart valve stent.

The disengaging of the mechanically stable connection between positioning stent **20** and heart valve stent **10** by means of external manipulation, in the case of valve dysfunction for example, is possible when the previously implanted heart valve stent **10** exhibits a retrievable structure suitable for this purpose. This could consist of a plurality of connecting struts which project medially from the upper outer end of the stent into the vascular lumen and join there with an anchoring device (eyelet, hook, nub, etc.). Should this anchoring device now be grasped by the retrieval catheter wire of catheter **30**, the distal portion of heart valve stent **10** can thus be compressed toward the lumen and drawn into a catheter tube **33**. This then again provides the opportunity of using the positioning stent **20** which remains as a marking and anchoring base for a new heart valve stent **10**.

The positioning stent **20** is made from a solid mesh (wire, polymer, etc.) or produced in a laser-cutting process. Applicable as suitable materials for the positioning stent are NiTi, high-grade steel or biocompatible plastics. For spatial orientation, x-ray markers can furthermore be disposed on positioning stent **20**.

The invention claimed is:

1. A valve prosthesis, comprising:

a self-expandable outer stent component including exactly three struts configured for placement between each of three respective portions of a native aortic valve and an aorta wall upon implantation of the valve prosthesis relative to the native aortic valve;

a self-expandable inner stent component coupled to the self-expandable outer stent component at a distal end of the outer stent component configured to be positioned farther from a native heart than a proximal end of the outer stent component, at least a portion of the inner stent component being radially inward of the struts, the valve prosthesis configured to receive the three portions of the native aortic valve between the respective three struts and the inner stent component upon implantation of the valve prosthesis relative to the native aortic valve; and

a prosthetic valve component coupled to the self-expandable inner stent component.

2. The valve prosthesis of claim **1**, wherein the prosthetic valve component is configured to function as the native aortic valve upon implantation of the valve prosthesis relative to the native aortic valve.

3. The valve prosthesis of claim **1**, wherein the valve prosthesis has a collapsed configuration and includes a plurality of attachment elements for attachment to a catheter in the collapsed configuration.

4. The valve prosthesis of claim **3**, wherein the attachment elements include eyelets.

5. A valve prosthesis, comprising:

an outer stent component including exactly three struts equidistant to one another, the exactly three struts configured for placement between three respective portions of a native aortic valve and an aorta wall upon implantation of the valve prosthesis relative to the native aortic valve, each strut having an apex pointing in the proximal direction towards a native heart;

an inner stent component coupled to the outer stent component, at least a portion of the inner stent component being radially inward of the struts to receive the respective three portions of the native aortic valve between the three struts and the inner stent component upon implantation of the valve prosthesis relative to the native aortic valve; and

a prosthetic valve component coupled to the inner stent component;

wherein the valve prosthesis is configured to maintain a position relative to the native aortic valve by holding the portions of the native heart valve between the inner stent component and the outer stent component.

6. The valve prosthesis of claim **5**, wherein both of the outer stent component and the inner stent component are self-expandable.

7. The valve prosthesis of claim **5**, wherein the inner stent component is coupled to the outer stent component at a distal end of the outer stent component configured to be positioned farther from a native heart than a proximal end of the outer stent component.

8. The valve prosthesis of claim **7**, wherein the inner stent component is coupled to the outer stent component at distal ends of the struts.

9. The valve prosthesis of claim **5**, wherein the inner stent component includes a plurality of first elements and the outer stent component includes a plurality of second elements, the first elements being complementary to the second elements to couple the inner stent component to the outer stent component.

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